DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

BIOMERIEUX
JOHN ALBRIGHT
REGULATORY AFFAIRS MANAGER
595 ANGLUM ROAD
HAZELWOOD MO 63042-2320

July 9, 2015

Re: K141133
Trade/Device Name: VIDAS *H. pylori* IgG, VIDAS 3, VIDAS Lyme IgG II, VIDAS RUB IgG, VIDAS TOXO M, VIDAS Human Chorionic Gonadotropin, VIDAS T4, VIDAS Testosterone, VIDAS TSH, and VIDAS D-Dimer Exclusion II
Regulation Number: 21 CFR 866.3110
Regulation Name: *Campylobacter fetus* serological reagents
Regulatory Class: I
Product Code: LYR, JJE, LSR, LFX, LGD, DHA, KLI, CDZ, JLW, DAP
Dated: June 15, 2015
Received: June 16, 2015

Dear Mr. Albright:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141133

Device Name
VIDAS H. pylori IgG, VIDAS 3, VIDAS Lyme IgG II, VIDAS RUB IgG, VIDAS TOXO IgM, VIDAS Human Chorionic Gonadotropin, VIDAS T4, VIDAS Testosterone, VIDAS TSH, and VIDAS D-Dimer Exclusion II

Indications for Use *(Describe)*

For VIDAS H. pylori IgG:
VIDAS® H. pylori IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of anti-Helicobacter pylori IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS HPY assay is intended as an aid in diagnosis of H. pylori infection in an adult symptomatic population.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS 3:
The VIDAS 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application configuration).
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS Lyme IgG II:
The VIDAS Lyme IgG II (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to Borrelia burgdorferi in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with B. burgdorferi. All VIDAS Lyme IgG II positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with B. burgdorfei.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS RUB IgG:
The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the instruments of the VIDAS family for the in vitro quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS RUB IgG (RBG) assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS TOXO IgM:
The VIDAS® TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS family (VITEK ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-Toxoplasma gondii IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti-Toxoplasma gondii lgG antibody assay. VIDAS TOXO IgM (TXM) assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS Human Chorionic Gonadotropin:
The VIDAS® HCG (HCG) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human Chorionic Gonadotropin (hCG) concentration in human serum or plasma. The VIDAS HCG (HCG) assay is intended to aid in the early detection of pregnancy.

This device is an in vitro diagnostic medical device for professional use only.

For VIDAS T4:
The VIDAS® T4 (T4) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS Testosterone:
The VIDAS Testosterone (TES) assay is an automated quantitative test for use on the instruments of the VIDAS family for the enzyme immunoassay measure of total testosterone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS TSH:
The VIDAS® TSH (TSH) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of human thyroid stimulating hormone- (TSH) concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.
This device is an in vitro diagnostic medical device for professional use only.

For VIDAS D-Dimer Exclusion II:
VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate, CTAD) using the ELFA technique (Enzyme Linked Fluorescent Assay).
VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.
This device is an in vitro diagnostic medical device for professional use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

According to the 21 CFR 807.92, this 510(k) summary aims to provide an understanding of the basis for a determination of substantial equivalence.

Assigned 510(k) number: K141133

A1. Owner information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B1. Device Name

Trade Name:	VIDAS® H.*pylori* IgG
Common Name:	H.*pylori* IgG
Classification name:	Campylobacter fetus serological reagents
Classification panel:	Microbiology
Governing Regulation:	21 CFR 866.3110
Device Classification:	Class I
Product code:	LYR

C1. Predicate Device

VIDAS H.*pylori* IgG (K001460)

D1. Device Description

The assay principle combines a 2-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). All of the assay steps as well as the assay temperature are controlled automatically by the instrument. The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips. After preliminary wash and sample dilution steps, the sample is cycled in and out of the SPR for a specified length of time. IgG antibodies to *H. pylori* present in the specimen will bind to the *H. pylori* antigen coating the interior of the SPR. Unbound sample components are washed away.

Anti-human IgG antibodies conjugated with alkaline phosphatase are cycled in and out of the SPR and will attach to any human IgG bound to the SPR wall. A final wash step removes unbound anti-human antibody conjugate. During the final detection step, the substrate (4 Methylumbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a

fluorescent product (4-Methylumbelliferone), the fluorescence of which is measured at 450 nm. The intensity of fluorescence is measured by the optical scanner in the instrument. At the end of the assay, results are automatically calculated by the instrument, a test value is generated and a report is printed for each sample.

E1. Intended Use

VIDAS® *H. pylori* IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of anti-*Helicobacter pylori* IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.

This device is an in vitro diagnostic medical device for professional use only.

F1. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	**New Device** **VIDAS H. *pylori***	**Predicate (K001460)** **VIDAS H. *pylori***
Intended Use	VIDAS® *H. pylori* IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of anti-*Helicobacter pylori* IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.	Same
Sample type	Serum or plasma	Same
Analyte	H.*pylori* IgG	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	30 Strips, 1x30 SPRs, 1 Standard (liquid), 1 Positive Control (liquid), 1 Negative Control (liquid)	Same (no change to assay).
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G1. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS *H. pylori* IgG assay on the VIDAS 3 to the VIDAS *H. pylori* IgG assay on the VIDAS. One reagent lot, one of each instrument and 250 serum samples including positive, equivocal and negative samples were used, and results were evaluated according to CLSI EP12-A2 guideline "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	122	3	0	125
	Equivocal	0	6	4	10
	Negative	0	2	113	115
	Total	122	11	117	250

Associated percent agreements and their 95% two-sided score confidence intervals (CI) are calculated in the table below :

Category	**Samples of interest/Total**	**Percent Agreement 2-sided 95% CI**
Negative	113/117	96.6% [91.5 ; 98.7] %
Positive	122/122	100% [96.9 ; 100.0] %

Precision

Three serum samples with samples close to the assay cut-off and moderate positive samples were tested in triplicate (3 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2 *"Evaluation of Precision Performance of Quantitative Measurement Methods" and* CLSI EP12-A2 "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline – Second Edition"*. The results were as follows:

	Sample 1		**Sample 2**		**Sample 3**	
	N = 108		**N = 108**		**N = 108**	
	Mean Test Value (TV) 0.76		**Mean Test Value (TV) 1.26**		**Mean Test Value (TV) 2.23**	
	SD	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Within-RUN (Repeatability)	0.06	7.7	0.08	6.2	0.12	5.2
Between-RUN	0.04	5.7	0.04	3.0	0.04	1.7
Between-DAY	0.00	0.0	0.00	0.0	0.05	2.4
Between-CALIBRATION	0.01	2.0	0.03	2.0	0.05	2.1
Between-INSTRUMENT	0.02	2.4	0.00	0.0	0.05	2.3

	Sample 1		Sample 2		Sample 3	
	N = 108		N = 108		N = 108	
	Mean Test Value (TV) 0.76		Mean Test Value (TV) 1.26		Mean Test Value (TV) 2.23	
	SD	CV (%)	SD	CV (%)	SD	CV (%)
Total Between-CALIBRATION	0.07	9.8	0.09	7.2	0.14	6.4
Total Between-INSTRUMENT	0.08	10.1	0.09	7.2	0.15	6.8

H1. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS H.*pylori* Assay is substantially equivalent to the predicate device identified in Item C1 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A2. Owner information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B2. Device Name

Trade Name:	VIDAS® 3
Common Name:	VIDAS 3
Classification name:	Analyzer, chemistry (photometric, discrete), for clinical use
Classification panel:	Clinical Chemistry
Governing Regulation:	21 CFR 862.2160
Device Classification:	Class I
Product code:	JJE

C2. Predicate Device Name

Trade Name:	VITEK IMMUNODIAGNOSTIC ASSAY SYSTEM (VIDAS)

D2. Device Description

The VIDAS® 3 instrument is an automated multiparametric immunoassay system, which uses ELFA (Enzyme Linked Fluorescent Assay) technology. The VIDAS 3 system offers primary tube sampling, automated sample dilution, reagent/sample detection and reagent traceability.

The technology used, which is adaptable to a wide range of assays, combines the EIA method with a final fluorescence reading: this technology is known as ELFA (Enzyme Linked Fluorescent Assay). The enzyme used in the VIDAS product range is alkaline phosphatase, which catalyzes the hydrolysis of the substrate 4-methyl umbelliferyl phosphate (4-MUP) into a fluorescent product 4-methyl umbelliferone (4-MU) the fluorescence of which is measured at 450nm. The immunological methods are either indirect EIA, immunocapture, sandwich or competition, all involving a conjugate using the alkaline phosphatase.

E2. Intended Use

The VIDAS 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application configuration).

This device is an in vitro diagnostic medical device for professional use only.

F2. Technological Performances Summary

Component	New Device VIDAS 3	Predicate (K891385) VIDAS Instrument
Trade Name	VIDAS 3	VIDAS
Indications for Use	The VIDAS 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application configuration). This device is an in vitro diagnostic medical device for professional use only.	The VIDAS® is a compact automated multiparametric immunoanalyzer that using predispensed disposable reagent strips and specially coated Solid Phase Receptacles (SPRs), can pipette, mix, incubate, control and analyze samples for in vitro diagnostic purposes. The VIDAS is only dedicated to be used in combination with VIDAS reagents range, designed and produced by bioMérieux. The technology used, which is adaptable to a wide range of assays, combines the EIA method with a final fluorescence reading: this technology is known as ELFA (Enzyme Linked Fluorescent Assay). The enzyme used in the VIDAS product range is alkaline phosphatase, which catalyzes the hydrolysis of the substrate 4-methyl umbelliferyl phosphate (4-MUP) into a fluorescent product 4-methyl umbelliferone (4-MU) the fluorescence of which is measured at 450nm. The immunological methods are either indirect EIA, immunocapture, sandwich or competition, all involving a conjugate using the alkaline phosphatase. This device is an in vitro diagnostic medical device for professional use only.
Technology	Automated multiparametric immunoassay system which uses ELFA (Enzyme Linked Fluorescent Assay) technology.	Same
# Sections	4	5
Reagent slots per section	3	6

Component	New Device VIDAS 3	Predicate (K891385) VIDAS Instrument
Total # samples that can be run simultaneously	12	30
Monitor	Peripheral (Attached)	Peripheral
Computer	Peripheral	Peripheral
Keyboard	Peripheral	Peripheral
Printer	Peripheral	Peripheral
Instrument Components	All unique or updated components are verified to not affect reagent performance.	All unique or updated components are verified to not affect reagent performance.
Components (Scanner head)	The scanner head is an instrument sub-system that's primary function is to perform the optical reading of the fluorescence as generated by the immunoassay reaction.	Same
Components (Software)	The user Software functions include: entry of patient data; run execution; data reduction and interpretation through a computation engine; edition of results; system supervision; management of calibrations and controls; validation of results; management of patient records.	While the VIDAS 3 software is unique to the VIDAS 3, it offers the same basic functions as the VIDAS software and uses the same computation engine.
Components (Reagents)	VIDAS reagents are comprised of predispensed disposable reagent strips and specially coated Solid Phase Receptacles (SPRs).	Same
Reagent (Principle of Operation)	Each VIDAS assay has been designed to be run on any of the three VIDAS family instruments. Each assay has a unique protocol (volumes, sequence of steps, incubation times, etc) that is independent of the instrument.	Same
Reagent	The assay intended use, clinical utility, principle of operation, kit composition, kit stability, kit storage conditions, calibration type, calibration frequency, sample type, sample volume, calculation of results, and interpretation of results are all independent of the instrument.	Same
Reagent Loading	Manual	Same
SPR/Strip synchronization	Automated confirmation	Manual
Sample Pipetting	Manual or automated	Manual
Sample dilutions	Manual or automated	Manual
Execution of the assay protocol	Each assay has its own pre-defined protocol that defines the sequence of assay steps (e.g. volumes, incubation times, order of steps).	Same
Enzymatic Reading	The reading made by the scanner head is based on the 4-methylumbelliferone (4-MU) fluorescent product located in the optical cuvette of the reagent strip after the enzymatic reaction has occurred.	Same

Component	New Device VIDAS 3	Predicate (K891385) VIDAS Instrument
Calculation and Interpretation of results	Data reduction of the fluorescence measurement is based upon computation engine and a knowledge base including assay and lot specific information.	Same
Unload Strips / SPRs	After completion of the run, the user manually removes the reagent Strips and SPRs.	Same
Unload other reagents and waste	Manual	Not applicable

G2. Performance Data

The VIDAS 3 performance testing was demonstrated through assay performance testing, using VIDAS D-Dimer Exclusion II, VIDAS H. pylori, VIDAS Human Chorionic Gonadotropin, VIDAS Lyme IgG II, VIDAS RUB IgG, VIDAS T4, VIDAS Testosterone, VIDAS TOXO M, and VIDAS TSH assays as the representative assays. This assay performance testing, which included method comparison, precision, detection limits, and linearity, demonstrated equivalency of the VIDAS 3 to the VIDAS and that running a VIDAS assay on either the VIDAS instrument or the VIDAS 3 instrument has no significant impact on the assay results.

H2. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS 3 is substantially equivalent to the predicate device identified in Item C2 of this summary.

A3. Owner information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B3. Device Name

Trade Name:	VIDAS® Lyme IgG II
Common Name:	Lyme IgG
Classification name:	Treponema pallidum treponemal test reagents
Classification panel:	Microbiology
Governing Regulation:	21 CFR 866.3830
Device Classification:	Class II
Product code:	LSR

C3. Predicate Device

VIDAS® Lyme IgG (K122986)

D3. Device Description

The VIDAS Lyme IgG II assay principle combines a 2-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA) (see User's Manual). The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times.
After a preliminary wash step and a sample dilution step, the antibodies to B. *burgdorferi* present in the specimen will bind to the B. *burgdorferi* specific recombinant proteins coating the interior of the SPR.
Unbound sample components are washed away. Antihuman IgG antibodies conjugated with alkaline phosphatase, will attach to the immunocomplex bound to the SPR wall.
A final wash step removes unbound conjugate. During the final detection step, the substrate (4-Methylumbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methylumbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the quantity of anti-B. *burgdorferi* IgG antibody present in the sample.
At the end of the VIDAS Lyme IgG II assay, results are automatically calculated by the instrument. A test value is generated and a report is printed.

E3. Intended Use

The VIDAS Lyme IgG II (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG II positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.

This device is an in vitro diagnostic medical device for professional use only.

F3. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS Lyme IgG II	Predicate (K122986) VIDAS Lyme IgG
Intended Use	The VIDAS Lyme IgG II (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG II positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.	Same
Sample type	Serum or plasma	Same
Analyte	Lyme IgG	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (liquid), 1 Control (liquid)	Same
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G3. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS Lyme IgG II assay on the VIDAS 3 to the VIDAS Lyme IgG II assay on the VIDAS. One reagent lot, one of each instrument and 220 serum samples including positive and negative samples were used, and results were evaluated according to CLSI EP12-A2 guideline "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table

		VIDAS		
		Positive	Negative	Total
VIDAS 3	Positive	109	0	109
	Negative	1	110	111
	Total	110	110	220

Associated percent agreements and their 95% two-sided score confidence intervals are presented in the table below:

Category	**Samples of Interest/Total**	**Percent Agreement with 2-sided 95% CI**
Positive	109/110	99.09% [95.04;99.98] %
Negative	110/110	100.00% [96.70;100.00] %

Precision – VIDAS 3

Three serum samples were tested in triplicate (3 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The results were calculated according to CLSI EP5-A2 and were as follows:

Panel Member	N	Mean Index	Within-run		Between-run		Between-day		Total Between	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Sample 1	108	0.17	0.01	5.4	0.00	0.0	0.00	1.8	0.01	8.2
Sample 2	108	0.23	0.01	4.0	0.00	0.9	0.00	1.0	0.02	6.9
Sample 3	108	0.64	0.02	3.4	0.00	0.0	0.00	0.0	0.04	6.2

H3. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS Lyme IgG II Assay when used on VIDAS 3 instrument is substantially equivalent to the predicate device identified in Item C3 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A4. Owner information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B4. Device Name

Trade Name:	VIDAS® RUB IgG
Common Name:	Anti-Rubella IgG
Classification name:	Rubella virus serological reagents
Classification panel:	Microbiology
Governing Regulation:	21 CFR 866.3510
Device Classification:	Class II
Product code:	LFX

C4. Predicate Device

VIDAS® RUB IgG (K080766)

D4. Device Description

The VIDAS® RUB IgG (RBG) assay is an enzyme-linked fluorescent immunoassay (ELFA) that consists of a two step enzyme immunoassay sandwich method and a fluorescent detection. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are ready-to-use and are provided in sealed reagent strips. All assay steps are automated by the instrument. The assay reactions take place by pipetting up and down with the SPR through the wells of the reagent strip. The sample is initially diluted, and follows a first incubation step in the SPR, where anti-Rubella IgG antibodies present in the sample bind to the rubella antigen coating the interior of the SPR. After a wash step to eliminate any unbound component, a second incubation is performed using a monoclonal anti-human IgG alkaline phosphatase conjugate. Following another wash step, the detection substrate (4-methyl-umbelliferyl phosphate) is added to the SPR.
The enzyme conjugate catalyzes the hydrolysis of the substrate into a fluorescent product (4-methyl-umbelliferone), and its fluorescence is measured by the instrument. The intensity of the fluorescence is proportional to the concentration of rubella antibodies present in the sample. Results are automatically determined by the instrument based on the stored calibration curve and according to the CLSI® I/LA6-A recommended cut-off of 10 IU/mL. The assay is calibrated against the WHO 1st International Standard for anti Rubella Immunoglobulin, Human (1997).

E4. Intended Use

The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the instruments of the VIDAS family for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG (RBG) assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.

This device is an in vitro diagnostic medical device for professional use only.

F4. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS RUB IgG	Predicate (K080766) VIDAS RUB IgG
Intended Use	The VIDAS® RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the instruments of the VIDAS family for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS® RUB IgG (RBG) assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals	Same
Sample type	Serum	Same
Analyte	Anti-Rubella IgG	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (liquid), 1 Positive Control (liquid), 1 Negative Control (liquid)	Same (no change to assay).
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G4. Performance Data

Method Comparison – Quantitative

A study was conducted to verify the correlation of the VIDAS RUB IgG assay on the VIDAS 3 to the VIDAS RUB IgG assay on the VIDAS. One reagent lot, one of each instrument and 112 serum samples (ranging from 0 to 225 IU/mL) were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	91*	0.9791	-0.2245	0.9776
Passing Bablock	112	1.00	0.00	0.9821
Weighted Deming	89**	0.9640	-0.2343	0.9805
Passing Bablock	111**	1.00	0.00	0.9840

* 21 samples had an average concentration equal to zero for VIDAS 3 and/or VIDAS, and were excluded from the Weighted Deming analysis.
** After removal of outliers.

Method Comparison – Qualitative

A study was conducted to verify the correlation of the VIDAS RUB IgG assay on the VIDAS 3 to the VIDAS RUB IgG assay on the VIDAS. One reagent lot, one of each instrument and 220 serum samples including positive, equivocal and negative samples were used, and results were evaluated according to CLSI EP12-A2 guideline "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	111	0	0	111
	Equivocal	3	8	1	12
	Negative	0	1	96	97
	Total	114	9	97	220

Associated percent agreements and their 95% two-sided exact confidence interval are calculated in the table below:

Category	Samples of interest/Total	Percent Agreement 2-sided 95% CI
Negative	96/97	99% [94.4;99.8] %
Positive	111/114	97.4% [92.5;99.1] %

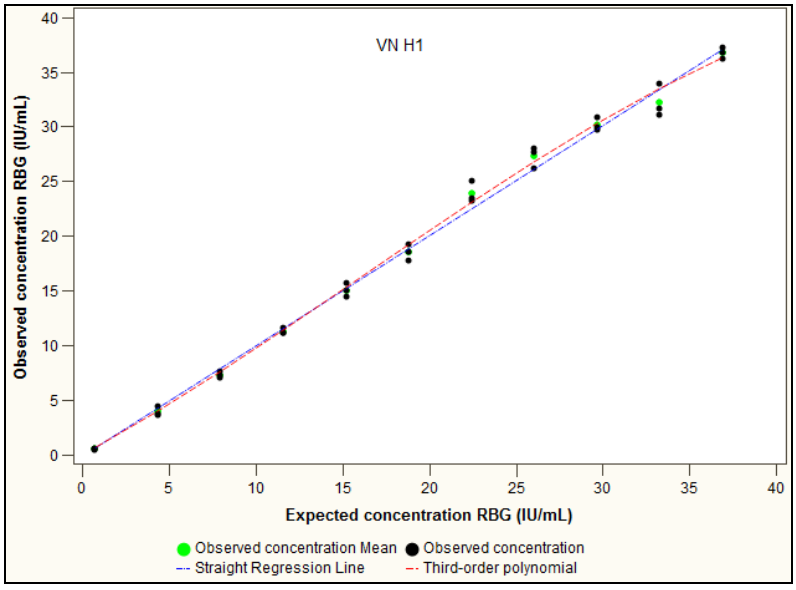
Precision

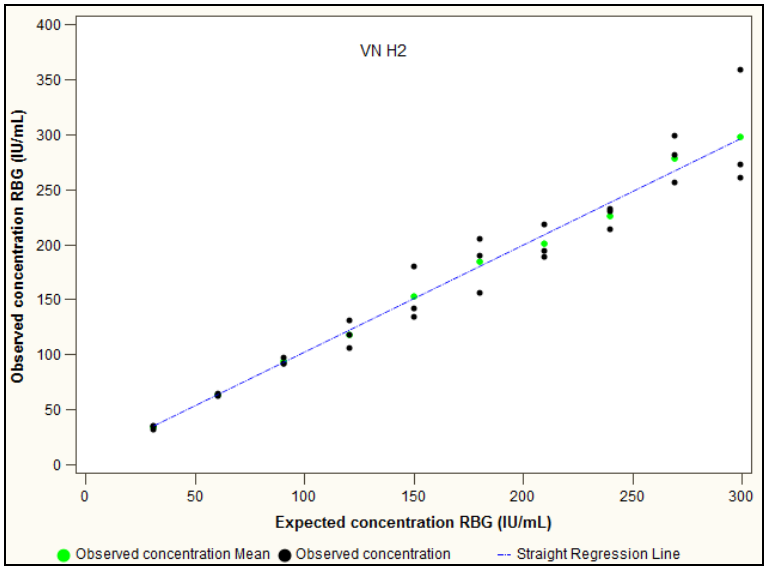
Five serum samples (with 2 samples close to the clinical decision points) were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (IU/mL) 2.69		Mean (IU/mL) 5.81		Mean (IU/mL) 12.82		Mean (IU/mL) 28.93		Mean (IU/mL) 132.88	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	0.41	15.2	0.55	9.5	0.74	5.7	2.39	8.3	10.24	7.7
Between-RUN	0.29	10.7	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
Between-DAY	0.00	0.0	0.00	0.0	0.19	1.5	0.43	1.5	0.00	0.0
Between-CALIBRATION	0.00	0.0	0.10	1.8	0.33	2.6	0.75	2.6	5.25	4.0
Between-INSTRUMENT	0.09	3.5	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
Total Between-CALIBRATION	0.50	18.6	0.56	9.7	0.83	6.5	2.54	8.8	11.51	8.7
Total Between-INSTRUMENT	0.51	18.9	0.56	9.7	0.83	6.5	2.54	8.8	11.51	8.7

Linearity

Two sample pools (VNH1 and VNH2) were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS RUB IgGa assay on VIDAS 3 is linear across the measuring range 0 - 250 IU/mL.





Detection Limits

The detection limits of the VIDAS RUB IgG assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS RUB IgG assay on the VIDAS 3 are as follows: LoB = 0.389 IU/mL; LoD = 0.595 IU/mL; LoQ = 0.608 IU/mL.

Assay Performance Testing using a CDC Panel

A CDC low-titer rubella antibody standard and a CDC reference panel (CDC RUB IgG serum panel) was tested using the VIDAS RUB IgG assay on the VIDAS 3 system and on the VIDAS system.

CDC low-titer rubella antibody standard results:

Vials of CDC low-titer reference standard were reconstituted with distilled water as preconized by CDC and then pooled as MSN (Master Stock Neat). According to the CDC information, the theoretical dose of the neat solution was 21 IU/mL. A ½ dilution solution was then prepared from the MSN solution and had an expected dose at 10.5 IU/mL.

The neat and 1/2 dilutions solutions of the CDC low titer standard (MSN & MS1/2 solutions) were then tested in triplicate in the same run on the VIDAS and the VIDAS 3 instruments using the same VIDAS RUB IgG reagent lot.

The mean result (IU/mL) obtained with the neat and 1/2 dilutions of the CDC low-titer standard and the difference in % compared to the theoretical/expected concentration of CDC low-titer standard were calculated for the VIDAS and the VIDAS 3:

- for VIDAS 3, the mean value of the neat and ½ dilution were respectively -11.0% and -11.4% compared to the theoretical concentration.
- for VIDAS, the mean value of the neat and ½ dilution were respectively -15.7% and -7.6% compared to the theoretical concentration.

CDC reference panel testing, data analysis and results:

The CDC reference panel consisted of 100 specimens, 50 pairs of sera titered by Hemagglutination Inhibition (9 negative sera resulting in 18 negative specimens and 41 positive sera resulting in 82 positive specimens). A single replicate of each of the 100 CDC reference panel samples was tested on the VIDAS and the VIDAS 3 instruments using the same VIDAS RUB IgG reagent lot.

The number of positive and negative sera detected are identical between VIDAS and VIDAS 3 systems: The VIDAS RUB IgG (RBG) assay identified 80/82 (97.6%) positive tests on 82 positive sera and 18/18 (100%) negative tests on 18 negative sera. One of the pairs of HI positive sera was reported as VIDAS equivocal (both results).

A5. Owner information

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Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B5. Device Name

Trade Name:	VIDAS® TOXO M
Common Name:	Anti-TOXO IgM
Classification name:	Toxoplasma gondiiserological reagents
Classification panel:	Microbiology
Governing Regulation:	21 CFR 866.3780
Device Classification:	Class II
Product code:	LGD

C5. Predicate Device

VIDAS® TOXO M (K923166)

D5. Device Description

The VIDAS TOXO IgM (TXM) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipettor for the assay. The SPR is coated with goat anti-μ chain antibodies. The VIDAS TOXO IgM (TXM) assay configuration prevents nonspecific reactions with the SPR.
Reagents for the assay are in the sealed TXM Reagent Strips. After a sample dilution step, the sample is cycled in and out of the SPR for a specified length of time. IgM antibodies present in the specimen will bind to the anti-μ chain antibodies coating the interior of the SPR. Unbound sample components are washed away. An immunocomplex of T. gondii antigen and mouse monoclonal anti-P30 antibodies conjugated with alkaline phosphatase is cycled in and out of the SPR and will attach to the human anti-T. gondii IgM bound to the SPR wall (Note: P30 is a major surface protein of the T. gondii tachyzoite, with molecular weight of 30,000 (5)). A final wash step removes unbound conjugate.
A fluorescent substrate, 4-methylumbelliferyl phosphate, is introduced into the SPR. Enzyme remaining on the wall of the SPR will catalyze the conversion of the substrate to the fluorescent product, 4-methylumbelliferone. The intensity of the fluorescence is measured by the optical scanner in the instrument.

When the VIDAS TOXO IgM (TXM) assay is completed, the results are analyzed automatically by the instrument, a test value is generated, and a report is printed for each sample.

E5. Intended Use

The VIDAS® TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS family (VITEK® ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-Toxoplasma gondii IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti-Toxoplasma gondii IgG antibody assay. VIDAS TOXO IgM (TXM) assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.

This device is an in vitro diagnostic medical device for professional use only.

F5. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS TOXO IgM	Predicate (K923166) VIDAS TOXO IgM
Intended Use	The VIDAS® TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS family (VITEK® ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-Toxoplasma gondii IgM antibodies in human serum, as an aid in the diagnosis of acute, recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti-Toxoplasma gondii IgG antibody assay. VIDAS TOXO IgM (TXM) assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.	Same
Sample type	Serum	Same
Analyte	Anti-Toxo IgM	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (liquid), 1 Control (liquid)	Same (no change to assay).
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G5. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS TOXO IgM assay on the VIDAS 3 to the VIDAS TOXO IgM assay on the VIDAS. One reagent lot, one of each instrument and 198 serum

samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Contingency table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	93	0	0	93
	Equivocal	2	4	0	6
	Negative	1	0	98	99
	Total	96	4	98	198

Associated percent agreements and their 95% two-sided score confidence intervals are calculated in the table below :

Category	**Samples of interest /Total**	**Percent Agreement 2-sided 95% CI**
Negative	98/98	100% [96.2;100.0] %
Positive	93/96	96.9% [91.2;98.9] %

Precision

Four serum samples were tested in 3 replicates twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**	
	N = 108		**N = 108**		**N = 108**		**N = 108**	
	Mean Index 0.47		**Mean Index 0.60**		**Mean Index 0.79**		**Mean Index 1.07**	
	SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Within-RUN (Repeatability)	0.01	3.0	0.02	3.0	0.02	2.7	0.03	2.7
Between-RUN	0.00	0.0	0.00	0.7	0.00	0.0	0.00	0.0
Between-DAY	0.00	0.0	0.00	0.5	0.01	0.9	0.01	1.1
Between-CALIBRATION	0.01	2.4	0.00	0.0	0.01	0.8	0.00	0.0
Between-INSTRUMENT	0.00	0.0	0.00	0.8	0.01	0.7	0.02	1.7
Total Between-CALIBRATION	0.02	3.9	0.02	3.2	0.02	3.0	0.03	2.9
Total Between-INSTRUMENT	0.02	3.9	0.02	3.3	0.02	3.1	0.04	3.4

A6. Owner information

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B6. Device Name

Trade Name:	VIDAS® Human chorionic gonadotropin
Common Name:	HCG
Classification name:	Human chorionic gonadotropin (HCG) test system
Classification panel:	Clinical Chemistry
Governing Regulation:	21 CFR 862.1155
Device Classification:	Class II
Product code:	DHA

C6. Predicate Device

VIDAS® HCG (K921302)

D6. Device Description

The VIDAS HCG (HCG) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-hCG antibodies. The VIDAS HCG (HCG) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing anti-hCG antibody conjugated with alkaline phosphatase.

The sample/conjugate mixture is cycled in and out of the SPR and the hCG will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the hCG concentration present in the sample. When the VIDAS HCG (HCG) assay is completed, the results are analyzed automatically by the instrument and a report is printed for each sample.

E6. Intended Use

The VIDAS® HCG (HCG) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human Chorionic Gonadotropin (hCG) concentration in human serum or plasma. The VIDAS HCG (HCG) assay is intended to aid in the early detection of pregnancy.

This device is an in vitro diagnostic medical device for professional use only.

F6. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS HCG	Predicate (K921302) VIDAS HCG
Intended Use	The VIDAS® HCG (HCG) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human Chorionic Gonadotropin (hCG) concentration in human serum or plasma to aid in the early detection of pregnancy.	The VIDAS HCG (HCG) assay is intended for use on the instruments of the VIDAS family (VITEK ImmunoDiagnostic Assay System) as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human Chorionic Gonadotropin (hCG) concentration in human serum or plasma for use in the early detection of pregnancy.
Sample type	Serum or plasma	Same
Analyte	HCG	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (lyophilized), 1 Control (lyophilized), 1 Diluent Buffer (liquid)	Same (no change to assay).
Measuring Range	2 - 1500 mIU/mL	Same
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G6. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS HCG assay on the VIDAS 3 to the VIDAS HCG assay on the VIDAS. One reagent lot, one of each instrument and 113 serum samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results, and the 95% Confidence Intervals (CI) were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	113	0.9265 [0.9043, 0.9488]	0.0828 [-0.1242, 0.2898]	0.9848 [0.9779, 0.9895]

Precision

Six serum samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6	
	N = 72		N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (mIU/mL) 4.46		Mean (mIU/mL) 6.46		Mean (mIU/mL) 9.48		Mean (mIU/mL) 74.43		Mean (mIU/mL) 311.52		Mean (mIU/mL) 1109.32	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	0.30	6.7	0.35	5.4	0.41	4.4	3.16	4.2	12.48	4.0	56.36	5.1
Between-RUN	0.12	2.7	0.20	3.1	0.13	1.4	0.73	1.0	0.00	0.0	0.00	0.0
Between-DAY	0.00	0.0	0.00	0.0	0.19	2.0	0.32	0.4	5.75	1.8	0.00	0.0
Between-CALIBRATION	0.08	1.7	0.26	4.1	0.12	1.3	2.36	3.2	5.59	1.8	32.71	2.9
Between-INSTRUMENT	0.08	1.7	0.00	0.0	0.23	2.4	0.00	0.0	0.00	0.0	0.00	0.0
Total Between-CALIBRATION	0.33	7.4	0.48	7.5	0.49	5.2	4.02	5.4	14.84	4.8	65.16	5.9
Total Between-INSTRUMENT	0.34	7.6	0.48	7.5	0.54	5.7	4.02	5.4	14.84	4.8	65.16	5.9

Linearity

Three sample pools were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS HCG assay on VIDAS 3 is linear across the measuring range 2 - 1500 mIU/mL.

Detection Limits

The detection limits of the VIDAS HCG assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS HCG assay on the VIDAS 3 are as follows: LoB = 0.242 mIU/mL; LoD = 0.571 mIU/mL; LoQ = 1.280 mIU/mL.

Carry-over

One high HCG positive sample was tested with one HCG batch analyte negative sample and one carry-over analyte negative sample during 7 runs on 3 VIDAS 3 instruments until 84 replicates of each sample was obtained. The average carry-over observed on VIDAS 3 and its 95% confidence interval were calculated and compared to a <5 PPM (parts per million) acceptance criteria.
The capacity of VIDAS 3 to not generate Carry-Over was demonstrated.

Dilution

Four samples (human serum pool) with the following approximate HCG concentrations 6 000, 25 000, 75 000, and 150 000 mUI/mL, were tested on two VIDAS 3 systems using an automated dilution sequence and a manual dilution sequence. For the automated dilutions, eleven (11) dilution levels ranging from 1/1 to 1/1000 were tested per sample. For the manual dilutions, two dilution levels were defined and tested per sample.

For each sample, each system and each dilution ratio, the average relative difference between the observed HCG concentration (automatic testing) and the estimated theoretical HCG concentration (manual testing) is estimated as follow:

Relative diff. (%) = 100 X (Observed dose – Theoretical dose) / Theoretical dose.

At a global level, the global average relative difference observed per dilution ratio ranges from -3.1% to +9.4%.

H6. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS HCG Assay is substantially equivalent to the predicate device identified in Item C6 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A7. Owner information

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Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B7. Device Name

Trade Name:	VIDAS® T4
Common Name:	T4
Classification name:	Total thyroxine test system
Classification panel:	Clinical Chemistry
Governing Regulation:	21 CFR 862.1700
Device Classification:	Class II
Product code:	KLI

C7. Predicate Device

VIDAS® T4 (K926393)

D7. Device Description

The VIDAS T4 (T4) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. At the time of manufacture, the SPRs are coated with mouse monoclonal anti-T4 antibodies. The VIDAS T4 (T4) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are in the sealed T4 Reagent Strips. The sample is transferred into the well containing the T4 antigen conjugated with alkaline phosphatase. The conjugate solution also contains ANS and sodium salicylate, which liberate bound T4 from the carrier proteins in the sample.

The sample/conjugate mixture is cycled in and out of the SPR and the T4 in the sample competes with the T4-alkaline phosphatase conjugate for binding with the mouse monoclonal anti-T4 antibodies coated on the SPR. Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled in and out of the SPR. Enzyme remaining on the SPR well will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone (450 nm). The intensity of fluorescence is measured by the optical scanner in the instrument. It is inversely proportional to the T4 concentration present in the sample. When the VIDAS T4 (T4) is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

E7. Intended Use

The VIDAS® T4 (T4) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.

This device is an in vitro diagnostic medical device for professional use only.

F7. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS T4	Predicate (K926393) VIDAS T4
Intended Use	The VIDAS® T4 (T4) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.	The VIDAS T4 (T4) assay is intended for use on the instruments of the VIDAS family (Vitek ImmunoDiagnostic Assay System) as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.
Sample type	Serum or plasma	Same
Analyte	T4	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (liquid), 1 Control (liquid)	Same
Measuring Range	6 – 320 nmol/L	Same
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G7. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS T4 assay on the VIDAS 3 to the VIDAS T4 assay on the VIDAS. One reagent lot, one of each instrument and 105 serum samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	105	0.9547	-0.6860	0.9866
Passing - Bablok	105	0.9523	-0.4397	0.9866

Precision

Five serum samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (nmol/L) 12.8		Mean (nmol/L) 35.14		Mean (nmol/L) 63.60		Mean (nmol/L) 121.99		Mean (nmol/L) 227.17	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	1.17	9.1	1.54	4.4	1.88	3.0	4.24	3.5	12.46	5.5
Between-RUN	0.00	0.0	0.00	0.0	0.62	1.0	1.53	1.3	0.00	0.0
Between-DAY	0.76	6.0	0.00	0.0	0.34	0.5	0.00	0.0	4.74	2.1
Between-CALIBRATION	0.51	4.0	0.95	2.7	1.44	2.3	1.05	0.9	4.13	1.8
Between-INSTRUMENT	0.00	0.0	0.00	0.0	0.00	0.0	0.48	0.4	0.00	0.0
Total Between-CALIBRATION	1.48	11.6	1.80	5.1	2.47	3.9	4.63	3.8	13.96	6.1
Total Between-INSTRUMENT	1.48	11.6	1.80	5.1	2.47	3.9	4.66	3.8	13.96	6.1

Linearity

One sample pool was serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS T4 assay on VIDAS 3 is linear across the measuring range 6 – 320 nmol/L.

Detection Limits

The detection limits of the VIDAS T4 assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS T4 assay on the VIDAS 3 are as follows: LoB = 1.596 nmol/L; LoD = 3.749 nmol/L; LoQ = 6.216 nmol/L.

H7. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS T4 Assay is substantially equivalent to the predicate device identified in Item C7 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A8. Owner information

Submitter's Name:	bioMérieux, Inc.
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Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B8. Device Name

Trade Name:	VIDAS® Testosterone
Common Name:	Testosterone
Classification name:	Testosterone test system
Classification panel:	Clinical Chemistry
Governing Regulation:	21 CFR 862.1680
Device Classification:	Class I
Product code:	CDZ

C8. Predicate Device

VIDAS® Testosterone (K021326)

D8. Device Description

The assay principle combines an enzyme immunoassay competition method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR®), serves as the solid phase as well as the pipetting device for the assay. Reagents for the assay are ready-to-use and predispensed in the sealed reagent strips. All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. The sample is taken and transferred into the well containing the conjugate which is an alkaline phosphatase-labeled testosterone derivative. The testosterone present in the serum and the testosterone derivative in the conjugate compete for the antitestosterone specific antibody sites coated to the inner surface of the SPR. Unbound components are eliminated during the washing steps.
During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is inversely proportional to the concentration of testosterone present in the sample. At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

E8. Intended Use

The VIDAS Testosterone (TES) assay is an automated quantitative test for use on the instruments of the VIDAS family for the enzyme immunoassay measure of total testosterone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

This device is an in vitro diagnostic medical device for professional use only.

F8. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS Testosterone	Predicate (K021326) VIDAS Testosterone
Intended Use	The VIDAS Testosterone (TES) assay is an automated quantitative test for use on the instruments of the VIDAS family for the enzyme immunoassay measure of total testosterone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.	VIDAS Testosterone is an automated quantitative test for use on the instruments of the VIDAS family for the enzyme immunoassay measure of total testosterone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.
Sample type	Serum or plasma	Same
Analyte	Testosterone	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	30 Strips, 1x30 SPRs, 1 Calibrator (lyophilized), 1 Control (lyophilized)	Same (no change to assay).
Measuring Range	0.1 – 13 ng/ml	Same
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G8. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS Testosterone assay on the VIDAS 3 to the VIDAS Testosterone assay on the VIDAS. One reagent lot, one of each instrument and 172 serum samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	172	0.9799	0.0030	0.9957
Passing - Bablok	172	0.9751	0.0085	0.9957

Precision

Five serum samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (ng/mL) 0.32		Mean (ng/mL) 1.80		Mean (ng/mL) 3.22		Mean (ng/mL) 5.17		Mean (ng/mL) 9.04	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	0.03	10.6	0.11	6.2	0.17	5.2	0.22	4.3	0.41	4.6
Between-RUN	0.01	4.5	0.08	4.2	0.10	3.2	0.00	0.0	0.12	1.3
Between-DAY	0.00	0	0.00	0.0	0.00	0.0	0.07	1.4	0.00	0.0
Between-CALIBRATION	0.03	8.1	0.12	6.9	0.15	4.5	0.22	4.3	0.39	4.3
Between-INSTRUMENT	0.04	11.4	0.00	0.0	0.05	1.4	0.17	3.2	0.15	1.7
Total Between-CALIBRATION	0.05	14.0	0.18	10.2	0.25	7.6	0.32	6.2	0.58	6.4
Total Between-INSTRUMENT	0.06	18.1	0.18	10.2	0.25	7.8	0.36	7.0	0.60	6.6

Linearity

Two sample pools were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS Testosterone assay on VIDAS 3 is linear across the measuring range 0.1- 13 ng/mL.

Detection Limits

The detection limits of the VIDAS Testosterone assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS Testosterone assay on the VIDAS 3 are as follows: LoB = 0.018 ng/mL; LoD = 0.035 ng/mL; LoQ = 0.088 ng/mL.

H8. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS Testosterone Assay is substantially equivalent to the predicate device identified in Item C8 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A9. Owner information

Submitter's Name:	bioMérieux, Inc.
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Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B9. Device Name

Trade Name:	VIDAS® TSH
Common Name:	TSH
Classification name:	Thyroid stimulating hormone test system
Classification panel:	Clinical Chemistry
Governing Regulation:	21 CFR 862.1690
Device Classification:	Class II
Product code:	JLW

C9. Predicate Device

VIDAS® TSH (K921816)

D9. Device Description

The VIDAS TSH (TSH) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-TSH antibodies. The VIDAS TSH (TSH) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing anti-TSH antibody conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the TSH will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the TSH concentration present in the sample.
When the VIDAS TSH (TSH) assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

E9. Intended Use

The VIDAS® TSH (TSH) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of human thyroid stimulating hormone- (TSH) concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.

This device is an in vitro diagnostic medical device for professional use only.

F9. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS TSH	Predicate (K921816) VIDAS TSH
Intended Use	The VIDAS® TSH (TSH) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of human thyroid stimulating hormone- (TSH) concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.	The VIDAS TSH (TSH) assay is intended for use on the instruments of the VIDAS family (Vitek® ImmunoDiagnostic Assay System) as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of human thyroid stimulating hormone- (TSH) concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.
Sample type	Serum or plasma	Same
Analyte	TSH	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (liquid), 1 Control (liquid), 1 Diluent Buffer (liquid)	Same (no change to assay).
Measuring Range	0.05 – 57 µIU/ml	0.05 – 60 µIU/ml
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G9. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS TSH assay on the VIDAS 3 to the VIDAS TSH assay on the VIDAS. One reagent lot, one of each instrument and 179 serum samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	179	1.0034	0.0042	0.9984
Passing Bablok	179	1.0028	-0.0001	0.9984

Precision

Six serum samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6	
	N = 72		N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (µIU/mL) 0.1		Mean (µIU/mL) 0.26		Mean (µIU/mL) 2.45		Mean (µIU/mL) 5.1		Mean (µIU/mL) 10.32		Mean (µIU/mL) 35.01	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-RUN (Repeatability)	0.00	5.1	0.01	2.5	0.05	2.0	0.10	2.0	0.20	2.0	0.70	2.0
Between-RUN	0.00	1.7	0.00	1.2	0.02	1.0	0.08	1.6	0.13	1.3	0.00	0.0
Between-DAY	0.00	0.0	0.00	1.7	0.02	0.8	0.00	0.0	0.00	0.0	0.19	0.5
Between-CALIBRATION	0.00	0.0	0.00	0.6	0.04	1.5	0.08	1.6	0.16	1.6	0.75	2.1
Between-INSTRUMENT	0.00	1.4	0.00	1.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
Total Between-CALIBRATION	0.01	5.4	0.01	3.3	0.07	2.8	0.15	3.0	0.29	2.8	1.04	3.0
Total Between-INSTRUMENT	0.01	5.5	0.01	3.4	0.07	2.8	0.15	3.0	0.29	2.8	1.04	3.0

Linearity

Four sample pools were serially diluted into a total of 8 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS TSH assay on VIDAS 3 is linear across the measuring range 0.05 – 57 µIU/mL.

Detection Limits

The detection limits of the VIDAS TSH assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS TSH assay on the VIDAS 3 are as follows: LoB = 0.019 µIU/mL; LoD/LoQ = 0.05 µIU/mL.

H9. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS TSH Assay is substantially equivalent to the predicate device identified in Item C9 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.

A10. Owner information

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Contact Person:	John Albright
Telephone number	314-731-8546
Fax number	314-731-8689
Date of Preparation:	July 6, 2015

B10. Device Name

Trade Name:	VIDAS® D-Dimer Exclusion II
Common Name:	D-Dimer
Classification name:	Fibrinogen and fibrin split products, antigen, antiserum, control
Classification panel:	Hematology
Governing Regulation:	21 CFR 864.7320
Device Classification:	Class II
Product code:	DAP

C10. Predicate Device

VIDAS® D-Dimer Exclusion II (K112818)

D10. Device Description

The VIDAS D-Dimer Exclusion II (DEXII) assay is an enzyme-linked fluorescent immunoassay (ELFA) performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with anti-Fibrin degradation product (FbDP) monoclonal antibodies. The VIDAS D-Dimer Exclusion II assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing an alkaline phosphatase-labeled anti-FbDP monoclonal antibody.

The sample/conjugate mixture is cycled in and out of the SPR and the antigen will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich". Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument; it is proportional to the D-Dimer concentration present in the sample. When the VIDAS D-Dimer Exclusion II assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

E10. Intended Use

VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate, CTAD) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.

This device is an in vitro diagnostic medical device for professional use only.

F10. Technological Performances Summary

A summary of the technological characteristics of the new device in comparison to those of the predicate device is presented in the table below.

Item	New Device VIDAS D-Dimer Exclusion II	Predicate (K112818) VIDAS D-Dimer Exclusion II
Intended Use	VIDAS® D-Dimer Exclusion II™ is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate, CTAD) using the ELFA technique (Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.	Same
Sample type	Plasma	Same
Analyte	D-Dimer	Same
Assay Technique	Enzyme-linked fluorescent immunoassay (ELFA)	Same
Kit Composition	60 Strips, 2x30 SPRs, 1 Calibrator (lyophilized), 2 Controls (lyophilized), 1 Diluent (liquid)	Same
Automated	Yes	Same
Instrumentation	VIDAS, miniVIDAS, VIDAS 3	VIDAS, miniVIDAS

G10. Performance Data

Method Comparison

A study was conducted to verify the correlation of the VIDAS D-Dimer Exclusion II assay on the VIDAS 3 to the VIDAS D-Dimer Exclusion II assay on the VIDAS. One reagent lot, one of each instrument and 219 plasma samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	219	0.9481	2.0974	0.9954
Passing Bablock	219	0.9394	5.1190	0.9954

Precision

Four plasma samples were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**	
	N = 72		**N = 72**		**N = 72**		**N = 72**	
	Mean (ng/mL) 73.73		**Mean (ng/mL) 243.06**		**Mean (ng/mL) 472.14**		**Mean (ng/mL) 6939.36**	
	SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Within-RUN (Repeatability)	2.36	3.2	6.66	2.7	10.04	2.1	114.20	1.6
Between-RUN	1.08	1.5	0.00	0.0	0.00	0.0	59.97	0.9
Between-DAY	0.00	0.0	0.45	0.2	0.00	0.0	0.00	0.0
Between-CALIBRATION	1.41	1.9	2.68	1.1	6.25	1.3	139.70	2.0
Between-INSTRUMENT	0.00	0.0	2.01	0.8	4.58	1.0	0.00	0.0
Total Between-CALIBRATION	2.96	4.0	7.20	3.0	11.83	2.5	190.14	2.7
Total Between-INSTRUMENT	2.96	4.0	7.47	3.1	12.68	2.7	190.14	2.7

Linearity

Two sample pools were serially diluted into a total of 11 and 15 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS D-Dimer Exclusion II assay on VIDAS 3 is linear across the measuring range 45 - 10000 ng/mL.

Detection Limits

The detection limits of the VIDAS D-Dimer Exclusion II assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS D-Dimer Exclusion II assay on the VIDAS 3 are as follows: LoB = 10.562 ng/mL; LoD = 16.251 ng/mL; LoQ = 17.229 ng/mL.

H10. Conclusion

The results for the performance testing submitted in this premarket notification are complete and demonstrate that the VIDAS D-Dimer Exclusion II Assay is substantially equivalent to the predicate device identified in Item C10 of this summary. The addition of the VIDAS 3 instrument to the VIDAS Family does not affect the safety and effectiveness of the Reagent kit.